ROI

Patented system

New exclusive LDR Medical concept

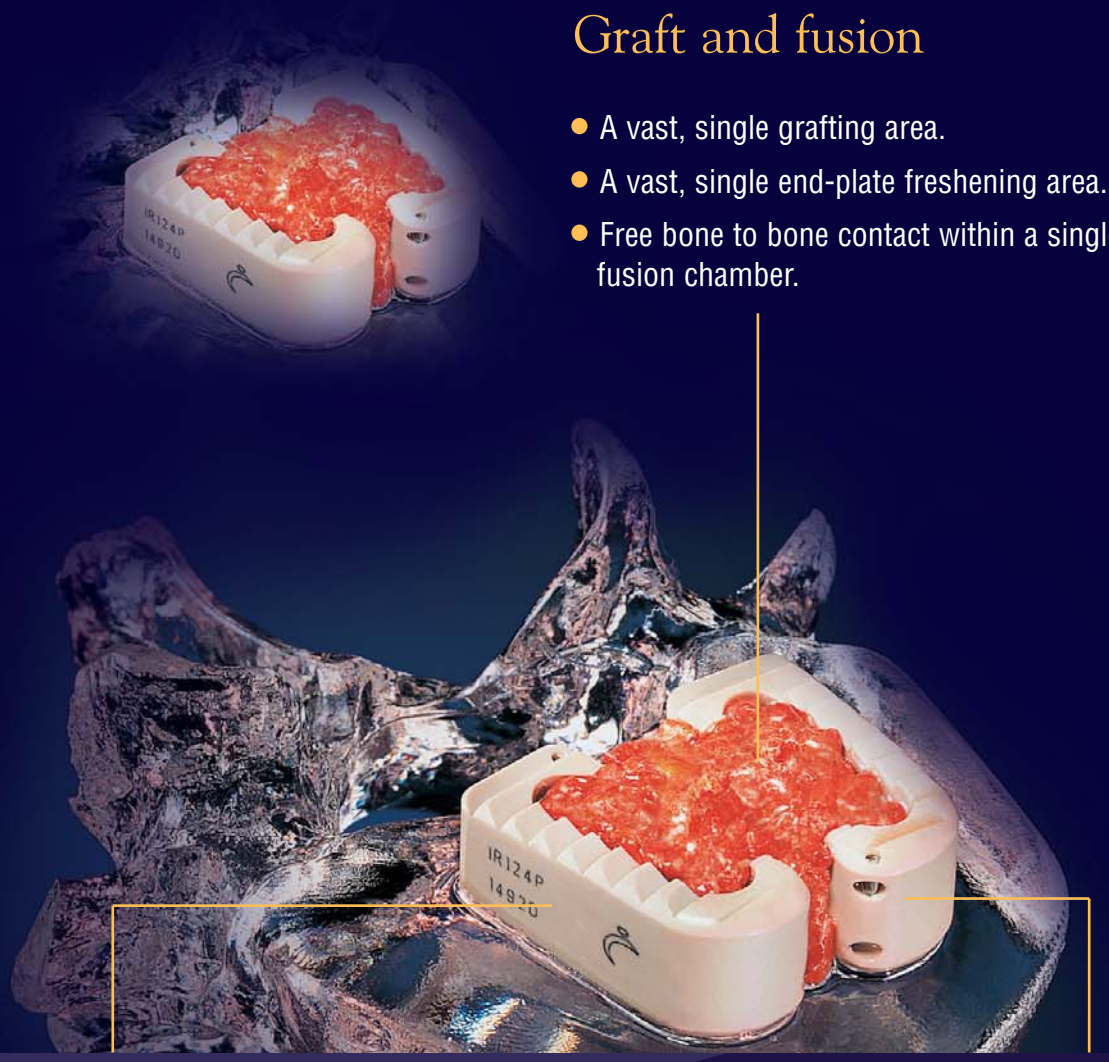
CE

The specifications of the roi implant aim at satisfying the requirements of lumbar intersomatic arthrodesis.

Roi intersomatic cages were designed for degenerative lumbar spinal surgery.

Using a posterior approach, the implant is introduced into the intervertebral space to enhance arthrodesis through bone fusion.

The open geometry of this intersomatic cage explains it's unique caracteristics which enhance the quality of bone graft.



Graft and fusion

- A vast, single grafting area.
- A vast, single end-plate freshening area.
- Free bone to bone contact within a single fusion chamber.

A passion for innovation

LDR médical

Technopole de l'Aube - BP 2 - 10902 Troyes Cedex 9 - France
Tel : +33 (0)3 25 82 32 63 - Fax : +33 (0)3 25 82 33 71
e-mail : ldrmedical@ldrmedical.fr
www.ldrmedical.fr

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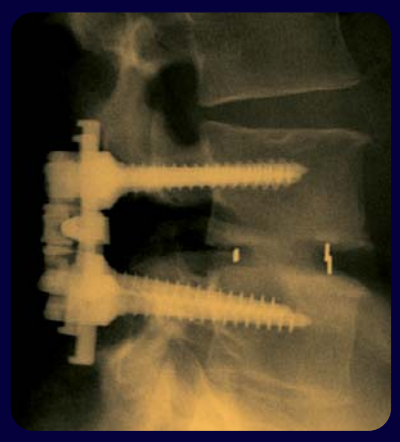
A passion for innovation

open radio transparent
intersomatic implant

ROI

A passion for innovation

Favour grafting by creating a fusion chamber



2 months post-op

Bone and fusion chamber having priority, a radio transparent material was mandatory for fusion follow-up and control.

Radio-transparency and safety

Transparency and consistency

- The biocompatibility and mechanical qualities of P.E.E.K. are now widely recognised in intersomatic applications.
- This material has an elasticity module close to that of bone, thus allowing the loading of the graft.
  There is also a biomechanical consistency between two vertebral segments, the fusion of which can be assessed and controlled over time by radio-transparency.

Safety

- ROI intersomatic cages are implanted according to a reproducible surgical technique which allows the progressive opening of the intersomatic space. As soon as they are placed, the serrated section of the implants ensures self-stability until the fusion is achieved.

Mechanical tests (by a certified independent laboratory)

- The excellent results show the reliability of the ROI implant which does not behave as a simple “spacer” but as a true fusion implant ensuring optimum conditions for bone fusion and harmonious distribution of constraints along the segment concerned.

Static compression tests

Number of tests	8	Average yield point	1000 daN
Breaking point	1492 daN		

Impaction tests

Number of tests	6
Average required energy at break	2.6 Joules

Dynamic compression tests

Number of tests	5	Frequency	5 Hz	Load	500 DaN	Number of cycles	5 millions

Implants controlled after each test showed no modifications.

A section pin-pointed within a complete range, an optimal weight-bearing surface allowing for safe loading, thus making it possible to restore and maintain intervertebral height as well as the restoration of the desired lordosis.

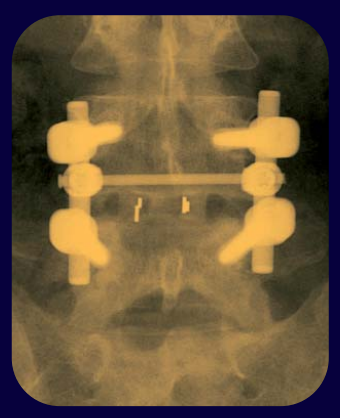
They allow radicular decompression by foramenal opening, plus stabilization and fusion of the spine in order to obtain the right spine statics.

ROI implants are used for surgical treatment of lumbar vertebral instability due to serious degenerative discopathies.

The most common surgical indications are : disc degeneration, stage 1 and 2 spondylolisthesis.

Radio-transparency and safety

- Transparency and biomechanically consistent.
- Excellent results in mechanical tests.



2 months post-op

Stability and anatomy

- A peripheral weight bearing surface outside the grafting area.
- Adjustment of lordosis based on the difference on antero-posterior heights of the implant.
- Maximum weight bearing area for optimum stability.

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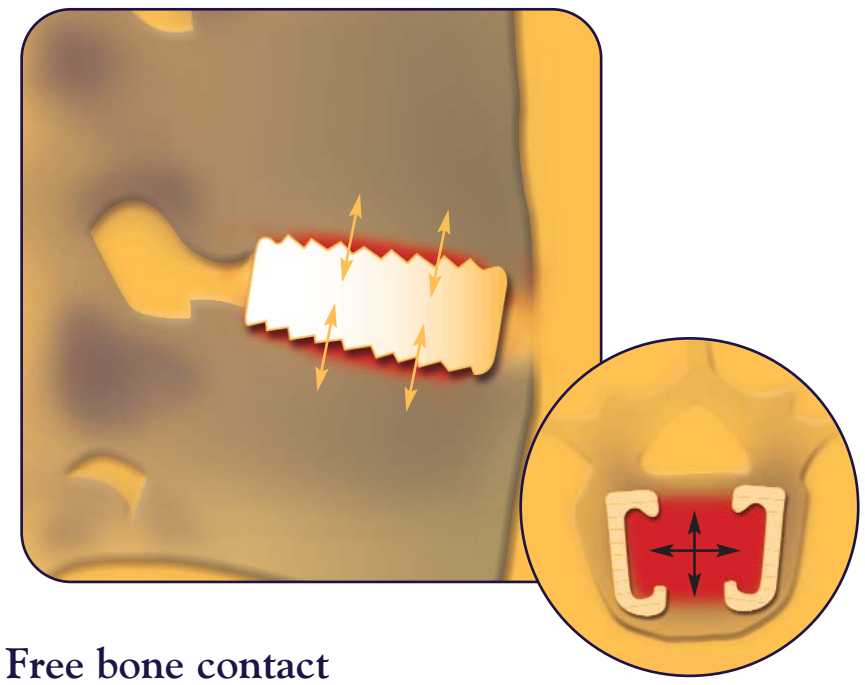
The ROI concept favours grafting by creating a single FUSION CHAMBER.

Graft and fusion

A single vast grafting area

- The quality and contact surface of the graft are essential for the success of a lumbar intersomatic arthrodesis by posterior approach.
- the ROI concept favours grafting by creating a single FUSION CHAMBER.

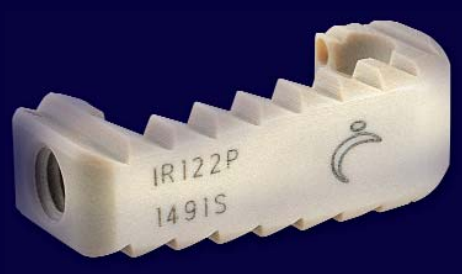


A vast and single end-plate freshening area.

- A meticulous freshening of vertebral end-plates allows an optimal bone-to-bone graft, thus favouring high quality fusion.
- The lateral opening of the implants optimises the vertebral end-plates freshening area thus favouring a large, single fusion chamber.
- The fusion of the graft will be all the more satisfactory, if it is mechanically stimulated.

Free bone contact within a single Fusion Chamber

- Free contact between the grafts within the open implants allows a “one-and-only” fusion block.
- The role of the implant-graft package is to enable vascularisation from one vertebral end-plate to the other over the largest possible grafting area.

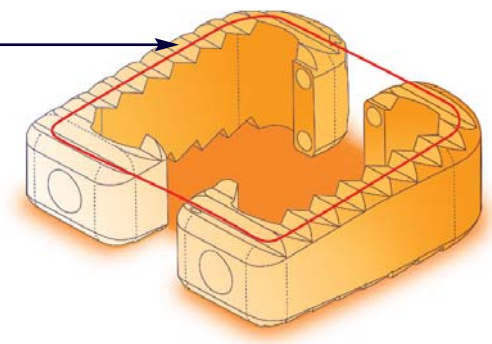


The ROI implant allows a restoration of the desired intersomatic space height thanks to a peripheral contact surface (external to the grafting area).

Stability and anatomy

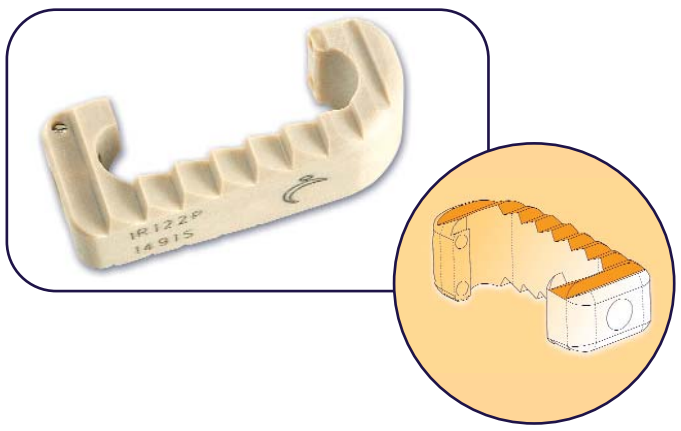
A peripheral support area outside the grafting area

- Restoring the intersomatic space height facilitates the opening of the foramen and makes it possible to obtain a radicular decompression.
- The ROI implant makes it possible to recreate an intervertebral space close to anatomy whilst respecting the grafting area and resting as close as possible to the peripheral border of the vertebral end-plate.



Adjustment of desired lordosis thanks to difference in antero-posterior height of the implant

- Restoration of desired lordosis is possible when placing an implant with a lordosing design. The ROI range is available in three angulations (0°, 5°, 8°). Implant’s anterior and posterior heights determine the desired lordosis.



Maximum contact surface for optimal stability

- Implants are shaped with a lateral opening allowing them to be thicker without reducing the grafting surface. Weight-bearing of the ROI implant is therefore applied on a wide, strong and intact bone surface (close to the peripheral border of the vertebral end-plate).

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A simple and user-friendly instrumentation ensuring the reproducibility of the operating processes.

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ROI instrumentation

Description	Reference
ROI BASIC INSTRUMENTATION SET	**IR 90**
Included	
Distractor 07 mm	**IR 900 R**
Distractor 08 mm	**IR 901 R**
Distractor 09 mm	**IR 902 R**
Distractor 10 mm	**IR 903 R**
Distractor 11 mm	**IR 904 R**
Distractor 12 mm	**IR 905 R**
Distractor 13 mm	**IR 906 R**
Distractor 14 mm	**IR 907 R**
Cage holder	**IR 912 R**
Threaded pin for cage holder	**IR 913 R**
Short cage holder	**IR 936 R**
Threaded pin for short cage holder	**IR 937 R**
Masselotte	**IR 914 R**
In situ spatula for bone graft	**IR 915 R**
Fenestrated round curette	**IR 935 R**
Graft compactor	**IR 917 R**
Bone graft support	**IR 918 R**
T handle for distractor	**IR 919 R**
Nerve root retractor 06 mm	**IR 921 R**
Nerve root retractor 10 mm	**IR 923 R**
Trial implant 0° 07 mm	**IR 925 R**
Trial implant 0° 09 mm	**IR 926 R**
Trial implant 0° 11 mm	**IR 927 R**

Description	Reference
Trial implant 5° 09 mm	**IR 929 R**
Trial implant 5° 11 mm	**IR 930 R**
Trial implant 5° 13 mm	**IR 931 R**
Trial implant 8° 09 mm	**IR 932 R**
Trial implant 8° 11 mm	**IR 933 R**
Trial implant 8° 13 mm	**IR 934 R**
OPTION	
Trial implant 0° 10 mm	**IR 938 R**
Trial implant 0° 12 mm	**IR 939 R**
Trial implant 5° 10 mm	**IR 940 R**
Trial implant 5° 12 mm	**IR 941 R**
Trial implant 8° 10 mm	**IR 942 R**
Trial implant 8° 12 mm	**IR 943 R**
Trial implant 8° 14 mm	**IR 944 R**
ROI Instrument box	**IR 990**

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ROI implants

Favour grafting by creating a fusion chamber

Description	Reference
ROI 0° (L 24 mm Implant)	
H 07 mm	**IR 102 P**
H 09 mm	**IR 104 P**
H 11 mm	**IR 106 P**
ROI 5° (L 24 mm Implant)	
H 09 mm	**IR 112 P**
H 11 mm	**IR 114 P**
H 13 mm	**IR 116 P**
ROI 8° (L 24 mm Implant)	
H 09 mm	**IR 122 P**
H 11 mm	**IR 124 P**
H 13 mm	**IR 126 P**
ROI Implant Rack	**EP 25**
OPTION	
ROI 0° (L 24 mm Implant)	
H 10 mm	**IR 105 P**
H 12 mm	**IR 107 P**
ROI 5° (L 24 mm Implant)	
H 10 mm	**IR 113 P**
H 12 mm	**IR 115 P**
ROI 8° (L 24 mm Implant)	
H 10 mm	**IR 123 P**
H 12 mm	**IR 125 P**
H 14 mm	**IR 127 P**

Option implants are manufactured upon request (3 months delivery)

Sterility and traceability

Optimised management

- Sterile packaging of implants allows their immediate use at delivery, without any additional processing. The daily management of implants is therefore tremendously simplified.

Sterile packaging

- All ROI implants are delivered in sterile packages, under double blister pack, with sterilization stickers.

Guarantee of mechanical properties

- Sterile packaging is the guarantee of a new implant. It ensures the harmlessness and the perfect operational condition of the implant.

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